



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

ATTY.'S DOCKET: SHALEV=2A

In re Application of:	)	Art Unit: 3762
	)	
Alon SHALEV et al.	)	Examiner:
	)	
Appln. No.: 10/753,882	)	Washington, D.C.
	)	
Filed: January 9, 2004	)	Confirmation No.
	)	
For: METHOD AND APPARATUS	)	May 13, 2004
FOR STIMULATING THE...	)	

**INFORMATION DISCLOSURE STATEMENT [IDS]**

Honorable Commissioner for Patents  
U.S. Patent and Trademark Office  
2011 South Clark Place  
Customer Window, Mail Stop DD  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, Virginia 22202

Sir :

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed:

[ ] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.

☒ B. before the mailing date of a first Office action on the merits or before the mailing of a first Office action after the filing of a Request for Continued Examination under 37 C.F.R. §1.114.

☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below).

☐ i. Counsel certifies that, upon information and belief, each item of information listed herein was either

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in §1.56(c) more than three months prior to the filing of this IDS.

***(use one and delete other of following)***

☐ ii. A check (check no. \_\_\_\_\_) for the fee set forth in §1.17(p), presently believed to be \$180, is enclosed. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035.

☐ ii. Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in §1.17(p), presently believed to be \$180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035.

☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant(s) state as follows under 37 CFR §1.97(e) for consideration of this IDS, that, upon information and belief, each item of information listed herein was either  
(Check one of the boxes "a" and "b" below)

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in §1.56(c) more than three months prior to the filing of this IDS.

2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., Form PTO/SB/08A) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate)

☐ A. Document(s) \_\_\_\_\_ is (are) deemed substantially cumulative to document(s) \_\_\_\_\_, and, in accordance with §1.98(c), only a copy of each of the latter documents is enclosed.

☒ B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120: 10/258,714, filed January 22, 2003

Applicant(s) identifies these documents by attaching hereto copies of the forms PTO-892 and PTO-1449 (or PTO/SB/08A) from the files of the prior application(s) or a fresh PTO-1449 (or PTO/SB/08A) listing these documents, and request that they be

considered and made of record in accordance with §1.98(d). Per 37 CFR §1.98(d), copies of these documents need not be filed in this application.

☐ C. Documents \_\_\_\_\_ are U.S. patents and/or published applications. As this is a U.S. application filed after June 30, 2003, or an entry into national stage under 35 USC §371 after June 30, 2003, the requirement to file copies of such U.S. patents or published applications has been waived. (Office of Patent Legal Administration - Pre O.G. Notice of July 11, 2003).

3. Document(s) \_\_\_\_\_ is (are) not in the English language. In accordance with §1.98(c), Applicant(s) states:

☐ An English translation of each document \_\_\_\_\_ (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.

☐ A concise explanation of the relevance of document(s) \_\_ is found in the attached \_\_\_\_\_ search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

☐ A concise explanation of the relevance of document(s) \_\_ is set forth as follows:

*(insert concise explanation of relevance)*

☐ A concise explanation of the relevance of document(s) \_\_ can be found on page(s) \_\_\_\_\_ of the specification.

☐ A concise explanation of document(s) \_\_\_\_\_ can be found on the attached sheet.

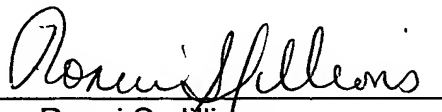
4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

5. Other information being provided for the examiner's consideration follows:

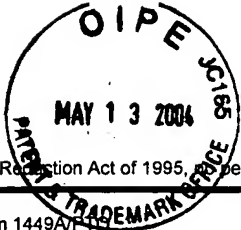
6. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant(s) reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant(s)

By:   
Ronni S. Jillions  
Reg. No. 31,979

RSJ:ft  
624 Ninth Street, N.W., Suite 300  
Washington, D.C. 20001-5303  
Telephone: (202)628-5197  
Facsimile: (202)737-3528  
G:\BN\C\colb\Shalev2A\Pto\13May04IDS.doc



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/1449B

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

**Complete if Known**

Application Number	10/753,882
Filing Date	January 9, 2004
First Named Inventor	Alon SHALEV
Group Art Unit	3762
Examiner Name	
Attorney Docket Number	SHALEV=2A

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA	US-4,152,928	05-08-1979	Roberts	
	AB	US-4,319,580	03-16-1982	Colley et al	
	AC	US-4,886,493	12-12-1989	Yee	
	AD	US-5,031,618	07-16-1991	Mullett	
	AE	US-5,855,907	01-05-1999	Peyman	
	AF	US-5,938,690	08-17-1999	Law et al.	
	AG	US-6,405,079 B1	06-11-2002	Ansarinia	
	AH	US-6,432,986	08-13-2002	Levin	
	AI	US-6,491,940, B1	12-10-2002	Levin	
	AJ	US-6,526,318 B1	02-25-2003	Ansarinia	
	AK	US-2003/0133877 A1	07-17-2003	Levin	
	AL	US-2001/0004644 A1	06-21-2001	Levin	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	AM	WO 00/44432	08-03-2000	Levin		
	AN	WO 01/43733	06-21-2001	Levin		
	AO	WO 99/03473	01-28-1999	Levin		

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	AP	BOLAY et al., "Intrinsic brain activity triggers trigeminal meningeal afferents in a migraine model," Nature Medicine 8:136-142 (February 2002)	
	AQ	BRANSTON, "The physiology of the cerebrovascular parasympathetic innervation", British Journal of Neurosurgery 9:319-329(1995)	

Examiner  
SignatureDate  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/753,882
				Filing Date	January 9, 2004
				First Named Inventor	Alon SHALEV
				Group Art Unit	3762
				Examiner Name	
Sheet	2	of	3	Attorney Docket Number	SHALEV=2A

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T <sup>2</sup>
	AR	Branston et al., "Contribution of cerebrovascular parasympathetic and sensory innervation to the short-term control of blood flow in rat cerebral cortex," J Cereb Blood Flow Metab 15(3):525-31 (1995)			
	AS	DELEPINE et al, "Plasma protein extravasation induced in the rat dura mater by stimulation of the parasympathetic sphenopalatine ganglion", Exp Neurol 147(2):389-400 (1997)			
	AT	FUSCO et al, "Capsaicin-sensitive' sensory neurons in cluster headache: pathophysiological aspects and therapeutic indication", Headache 34(3):132-137 (1994)			
	AU	HARA et al, "Parasympathetic cerebrovascular innervation: an anterograde tracing from the sphenopalatine ganglion in the rat", Neurosurgery 32(5):822-827 (1993)			
	AV	KROLL et al, "Outwitting the blood-brain barrier for therapeutic purposes: osmotic opening and other means", Neurosurgery 42(5):1083-1099 (1998)			
	AW	LAMBERT et al, "Decreased carotid arterial resistance in cats in response to trigeminal stimulation", J Neurosurg 61(2):307-315 (1984)			
	AX	MASINI et al, "Stimulation and resection of vidian nerve in patients with chronic hypertrophic non-allergic rhinitis: effect on histamine content in nasal mucosa," Agents and Actions 18:251-3 (1986)			
	AY	LEE et al, "Drug transporters in the central nervous system: brain barriers and brain parenchyma considerations", Pharmacol Rev 53(4):569-596 (2001)			
	AZ	MAJOR et al, "Odorants presented to the rat nasal cavity increase cortical blood flow", Chem Senses 24(6):665-669 (1999)			
	BA	RUCCI et al., "Effects of vidian nerve stimulation on the nasal and maxillary sinus mucosa," The Journal of Laryngology and Otology 98:597-607 (1984)			
	BB	RUCCI et al., "Histamine release from nasal mucosal mast cells in patients with chronic hypertrophic non-allergic rhinitis, after parasympathetic nerve stimulation," Agents Actions 25:314-20 (1988)			
	BC	RUCCI et al., "Tympanometric variations induced by vidian nerve stimulation in humans," The Journal of Laryngology and Otology 99:355-358 (1985)			
	BD	Rucci L et al., "Vidian nerve resection in chronic hypertrophic non allergic rhinitis: effects on histamine content, number and rate of degranulation processes of mast cells in nasal mucosa," Rhinology 23:309-314 (1985)			
	BE	RUSKELL GL, "The orbital branches of the pterygopalatine ganglion and their relationship with internal carotid nerve branches in primates," J Anat 106(2):323-339 (1970)			
	BF	SAMAD et al, "Interleukin-1 $\beta$ -mediated induction of Cox-2 in the CNS contributes to inflammatory pain hypersensitivity", Nature 410(6827):471-475 (2001)			
	BG	SANDERS et al, "Efficacy of sphenopalatine ganglion blockade in 66 patients suffering from cluster headache: a 12- to 70-month follow-up evaluation", Neurosurg 87(6):876-880 (1997)			
	BH	SEYLAZ et al., "Effect of stimulation of the sphenopalatine ganglion on cortical blood flow in the rat," J Cereb Blood Flow Metab 8:875-8 (1988)			
	BI	SILVER WL, "Neural and pharmacological basis for nasal irritation", Ann N Y Acad Sci 641:152-163 (1992)			
	BJ	SUZUKI et al, "Selective electrical stimulation of postganglionic cerebrovascular parasympathetic nerve fibers originating from the sphenopalatine ganglion enhances cortical blood flow in the rat", J Cereb Blood Flow Metab 10(3):383-391 (1990)			
	BK	SUZUKI et al, "Effect on cortical blood flow of electrical stimulation of trigeminal cerebrovascular nerve fibres in the rat", Acta Physiol Scand 138(3):307-316 (1990)			

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/753,882
		Filing Date	January 9, 2004
		First Named Inventor	Alon SHALEV
		Group Art Unit	3762
		Examiner Name	
Sheet 3	of 3	Attorney Docket Number	SHALEV=2A

BL	SUZUKI et al., in "Origins and pathways of cerebrovascular vasoactive intestinal polypeptide-positive nerves in rat," J Cereb Blood Flow Metab 8:697-712 (1988)	
BM	van de WATERBEEED et al, "Estimation of blood-brain barrier crossing of drugs using molecular size and shape, and H-bonding descriptors", J Drug Target 6(2):151-165 (1998)	
BN	TODA et al., "Cerebral vasodilation induced by stimulation of the pterygopalatine ganglion and greater petrosal nerve in anesthetized monkeys," Neuroscience 96(2):393-398 (2000)	
BO	TODA et al., "Preganglionic and postganglionic neurons responsible for cerebral vasodilation mediated by nitric oxide in anesthetized dogs," J Cereb Blood Flow Metab 20:700-708 (2000)	
BP	YOUNG, "Electrical stimulation of the trigeminal nerve root for the treatment of chronic facial pain," J Neurosurg 83:72-78 (1995)	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.